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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/071,829	02/07/2002	Mark Douglas Howell	704613-5001	4144

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EXAMINER	
LAM, ANN Y	
ART UNIT	**PAPER NUMBER**
1641	

DATE MAILED: 11/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/071,829	HOWELL ET AL.	
	Examiner	Art Unit	
	Ann Y. Lam	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 October 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *50-87* is/are pending in the application.

4a) Of the above claim(s) *75-79,82 and 87* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *50-74, 80, 81, 83-86* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 6, 2005 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 50-74, 80-81 and 83-86 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 50, line 9, recites "wherein binding partners in said extracorporeal system..." It is not clear whether these binding partners are the same as the "at least one binding partner" in line 4.

Claim 50 is also not clear as to whether or not *all* binding partners in the system are limited to the Markush group in lines 9-12. (Applicant's argument on page 12 of the

response stated that Applicant intends for any binding partner in the system to be limited to those in the recited Markush group. This would be clear if Applicant inserts "all" before "binding partners" in line 9, to which Applicant's attorney in the personal interview of November 10, 2005 said she is amenable to changing.)

For purposes of prosecution, Examiner will interpret claim 50 to mean that all binding partners in the system are limited to the Markush group in lines 9-12, as Applicant intended.

Claim 80, line 16, recites "binding partners". It is not clear whether these binding partners refer to the binding partner in line 7. (Claim 80 will similarly be interpreted to mean that all binding partners in the system are limited to the Markush group in lines 16-19.)

Claim 81, line 19, recites "binding partners". It is not clear whether these binding partners refer to the binding partner in line 7. (Claim 81 will similarly be interpreted to mean that all binding partners in the system are limited to the Markush group in lines 19-22.)

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

1. Claims 50-52, 54, 60-61 and 66-74 are rejected under 35 U.S.C. 102(a) as being anticipated by Mitteregger et al. "In Vitro Cell Culture Systems as the Basis for an Extracorporeal Blood Purification Strategy in Multiorgan Failure Treatment", Therapeutic Apheresis, 3(3):257-263, August 1999.

As to claim 50, Mitteregger et al. teach a device for reducing the amount of a targeted immune system inhibitor in blood, comprising

an absorbent matrix comprising an inert medium (i.e., specific immunoadsorbents, page 257, right column, last sentence; and page 258, right column, last sentence) attached to at least one binding partner (i.e., TNF alpha antibody, page 260, right column , last partial sentence; and page 261, right column, last partial paragraph) capable of specifically binding to a targeted immune system inhibitor,

and a conduit (wells, page 259, left column, last full sentence) for conducting the blood to the absorbent matrix to produce altered blood having a reduced amount of the targeted immune system inhibitor.

(Examiner notes that claim 50 is interpreted as if the receptor for tumor necrosis factor alpha and the receptor for tumor necrosis factor beta as two separate species in the Markush group.)

As to claim 51, the targeted immune system inhibitor is present in a plasma component of the blood (page 260, right column, last partial sentence.)

As to claims 52 and 54, the inert medium is a macroporous bead (i.e., magnetic beads, page 260, right column, last partial sentence.)

As to claim 60, the binding partner (i.e., the TNF alpha antibody) is a binding partner to which the targeted immune system inhibitor binds to in nature, or a fragment of the binding partner to which the targeted immune system inhibitor binds to in nature, wherein the fragment specifically binds to the targeted immune system inhibitor.

As to claims 61, the binding partner or fragment (i.e., the TNF alpha antibody) is capable of being produced recombinantly. (Examiner notes that even though Applicant claims that the binding partner is produced recombinantly, Applicant is claiming a device; and therefore the claim is examined as if it was a product-by-process claim. Therefore the prior art meets the claim since the Mitteregger antibody may be produced recombinantly.)

As to claim 66, the binding partner comprises a polyclonal antibody preparation or fragments that specifically bind to the targeted immune system inhibitor (page 261, right column, last paragraph, second sentence.)

As to claims 67 and 68, the binding partner comprising a plurality of different polyclonal antibody preparations (page 257, right column, last sentence; page 260, right column, last partial sentence; page 262, first full paragraph, last sentence).

As to claims 69 and 73, the binding partner (i.e., antibodies) may be produced synthetically. (Examiner notes that even though Applicant claims that the binding partner is a synthetic peptide, Applicant is claiming a device; and therefore the claim is examined as if it was a product-by-process claim. Therefore the prior art meets the claim since the Mitteregger antibody may be produced synthetically.)

As to claims 70 and 72,the synthetic peptide is conjugated to a carrier (i.e., the immunosorbent.)

As to claims 71 and 74, the binding partner comprises a plurality of synthetic peptides capable of specifically binding to the targeted immune system inhibitor (page 261, last paragraph.)

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 62-65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mitteregger et al., "In Vitro Cell Culture Systems as the Basis for an Extracorporeal Blood Purification Strategy in Multiorgan Failure Treatment", Therapeutic Apheresis, 3(3): 257-263, August 1999, in view of Skurkovich et al., 5,626,843.

Mitteregger et al. disclose the invention substantially as claimed (see above).

As to claims 62-65, Mitteregger et al. also do not teach that the tumor necrosis factor antibody is a monoclonal antibody. (Mitteregger et al. only teaches that the antibodies may be polyclonal, see page 261, last paragraph, second sentence.)

However, Skurkovich et al. teach that tumor necrosis factor can be removed from blood through monoclonal or polyclonal antibodies (col. 3, line 41; col. 2, line 65; see also col. 4, line 8).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize monoclonal antibodies to remove tumor necrosis factors in the Mitteregger et al. invention as an alternative to polyclonal antibodies because Skurkovich et al. teach monoclonal antibodies and polyclonal antibodies to tumor necrosis factors are functional equivalents in removing tumor necrosis factors.

3. Claims 58, 80, 81 and 83-86 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mitteregger et al., "In Vitro Cell Culture Systems as the Basis for an Extracorporeal Blood Purification Strategy in Multiorgan Failure Treatment", Therapeutic Apheresis, 3(3): 257-263, August 1999, in view of Skurkovich et al., 4,362,155.

Mitteregger et al. teach the invention substantially as claimed (see above).

With respect to claim 58, although Mitteregger et al. teach a microsphere based detoxification system and that another extracorporeal blood purification system may be used, (page 261, first paragraph), Mitteregger et al. however do not teach that the inert medium is a silica-based particle. Skurkovich et al. teach this limitation.

Skurkovich et al. teach a sorbent containing device for removing materials from blood (col. 4, lines 32-44.) Skurkovich et al. teach that the inert medium is glass beads (28.) (Glass is known to be silica-based.)

It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize silica-based particles as the inert medium generally disclosed by Mitteregger et al. because Skurkovich et al. teach that such materials provide the advantage of acting as a solid support for a sorbent to remove materials from blood components.

As to claims 80, 81 and 83-86, Mitteregger et al. also do not teach an apparatus for separating whole blood into a cellular component and an acellular component and (claims 83-86). However, this limitation is taught by Skurkovich et al.

Skurkovich et al. teach pumping blood into a separator to separate plasma from whole blood. The plasma is then fed from the separator to a sorbent containing device for removing materials from blood (col. 4, lines 32-44.)

It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize a blood separator as taught by Skurkovich et al. in the Mitteregger et al. invention because Skurkovich et al. teach that a blood separator connected to a sorbent containing device provides the advantage of facilitating removal of materials from blood plasma.

As to claim 84, Skurkovich teach that the acellular component or fraction thereof contains the targeted immune system inhibitor (col. 4, lines 37-41.)

As to claim 85, the conduit conducts the acellular component or fraction thereof to a absorbent matrix (60) to produce an altered acellular component or altered fraction thereof having a reduced amount of the targeted immune system inhibitor (col. 4, lines 38-41.) Patent '155 also teaches that the device (60) is a sorbent containing device,

which can be the means (14) for removing interferon, or a device for a method of using a sorbent for interferon carried by a solid support (see Skurkovich, col. 4., lines 38-44.)

As to claim 86, the system further comprises a conduit (62) for conducting the altered acellular component or fraction thereof from the absorbent matrix to the cellular component to produce an altered whole blood (see Skurkovich, col. 4, lines 45-49.)

4. Claims 53, 55-57 and 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mitteregger et al., "In Vitro Cell Culture Systems as the Basis for an Extracorporeal Blood Purification Strategy in Multiorgan Failure Treatment", Therapeutic Apheresis, 3(3): 257-263, August 1999, in view of Prusiner et al., 6,221,614.

Mitteregger et al. teach the invention substantially as claimed (see above.)

However Mitteregger et al. do not teach that the inert medium is a hollow fiber (claim 53), a cellulose-based fiber (claim 55), a synthetic fiber (claim 56), or a flat membrane (claim 57), or that the binding partner is covalently joined to an inert medium (claim 59.) However, Prusiner et al. teach these limitations.

Prusiner et al. teach an extracorporeal device to remove material from blood through complexing with an immobilized agent on a support (col. 8, lines 42-51), wherein the immobilized agent may be an antibody (col. 15, lines 37-38.) Prusiner further teaches that the support may be beads or other types (col. 8, line 50.) As to claim 53, Prusiner secifically teaches that the inert medium (support) is a hollow fiber (col. 13, line 50.) As to claim 55, Prusiner teaches that the inert medium may be a cellulose-based fiber (col. 16, line 13.) As to claim 56, the fiber may be produced

synthetically. (Examiner notes that Applicant claims that the fiber is a synthetic fiber. However, since Applicant is claiming a device, the claim is interpreted as if it was a product-by-process claim. Thus, the prior art meets the claim since the fiber may be produced synthetically.) As to claim 57, Prusiner et al. teach that the inert medium may be a flat membrane (col. 13, lines 48-49.)

It would have been obvious to one of ordinary skill in the art to provide a hollow fiber, cellulose-based fiber, or flat membrane as taught by Prusiner et al. as an alternative to the bead immunoadsorbents in the Mitteregger et al. device because Prusiner et al. teach that these types of supports are functional equivalents of beads for removing material from blood through immobilized antibodies.

As to claim 59, Prusiner et al. teach that the safest coupling between a complexing agent and a membrane is covalent coupling, which depends on the choice of membrane material and the nature of the complexing agent (col. 15, lines 58-67.)

It would have been obvious to one ordinary skill in the art at the time the invention was made to utilize covalent coupling as taught by Prusiner et al. to immobilize the antibody to the solid support in the Mitteregger et al. invention because Prusiner et al. teach that such type of coupling provide the advantage of removing material from blood.

Response to Arguments

Applicant's arguments are moot in view of the new grounds of rejections. Applicant has amended the claims with the intention that all binding partners in Applicant's invention are limited to those listed in the Markush group in the independent claims (thus excluding interferons as one of the binding partners). Mitteregger et al. teach an assay using beads coated with TNF alpha antibodies, to remove TNF alpha, one of the binding partners in Applicant's Markush group. The beads are not disclosed as having other types of binding partners

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is 571-272-0822. The examiner can normally be reached on M-Sat 11-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A.L.

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11/21/05